COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

6603 W. Broad Street, 5th Floor, Conference Room 2 (804) 662-9911
Richmond, Virginia 23230 (804) 662-9313

Tentative Agenda of Meeting

March 29, 2007
9:00 AM

TOPIC	PAGE(S)
Call to Order: John O. Beckner, Chairman	
• Reading of emergency evacuation script-Cathy Reiniers-Day	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	
◦ January 31, 2007	1-7
◦ January 31, 2007 Examination Committee Minutes	8-9
◦ March 7, 2007 Ad Hoc Regulation Review Committee Minutes	10-19
Call for public comment	
Regulations:	
• Update on regulations in process-Elaine Yeatts	to be distrubuted
• Adoption of proposed amendments to PPG regulations, 18 VAC 110-10-10 et seq.	20-31
Guidance Documents:	
• approval of a guidance document related to dispensing from a hospital chart order by a retail pharmacy for discharge medications-request from previous meeting	32-35
• development and approval of a guidance document related to non-resident entities that are involved in the manufacture or distribution of a prescription drug, but do not physically possess or directly distribute the drug into Virginia.	36-37
• request by Joe Leming for guidance document that addresses substitution of albuterol CFC inhalers with the HFA inhalers	38-41
Miscellaneous:	
• ExCPT exam-request for this exam to be a Board approved examination for pharmacy technician registration	42-43
• Request from Merck not to provide social security numbers for owners	44-49
• Request from Robert M. Wolin, attorney for DaVita Rx, non-resident pharmacies to dispense prescriptions for dialysis patients in Virginia and use approximately 53 dialysis centers as alternate delivery sites	50
• New pharmacies, how far in advance of opening should we inspect and issue the permit?	51

- Approval of form for verification of pharmacy supervisor for pharmacy interns 52-54
- Request from Disamodha Amarasinghe, MD to require pharmacies to have caller ID on phones and require checking of photo ID for patients when picking up prescriptions 53-60

Reports:

- Report on Board of Health Professions-Jennifer Edwards 61-69
- Report on Disciplinary Program-Faye Lemon, Director, Enforcement Division
- Executive Director's Report-Scotti Russell
  - report on disciplinary program-Cathy Reiniers-Day
  - report on licensing, inspections, website-Caroline Juran
  - report on the prescription monitoring program-Ralph Orr

New Business

Consideration of summary suspension(s)

Adjourn

***The Board will have a working lunch at approximately 12:00 noon**

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

January 31, 2007
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:10 a.m.

PRESIDING: John O. Beckner, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
Willie Brown
Jennifer H. Edwards
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

MEMBERS ABSENT:
Bobby Ison
Diane Langhorst

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Ralph Orr, Program Manager, Prescription Monitoring Program
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General (arrived 9:12)
Tiffany N. Mallory, Administrative Assistant

QUORUM: With eight members of the Board present, a quorum was established.

Ms. Reiniers-Day read the emergency evacuation procedure for Conference Room 2.

APPROVAL OF AGENDA: Mr. Brown moved and the Board voted unanimously to adopt the amended agenda distributed at the meeting.

APPROVAL OF MINUTES: The minutes of the September 27, 2006 Board Meeting were approved as presented.

REPORT OF DHP DIRECTOR, SANDRA W. RYALS

Ms. Ryals provided the Board with an update on several initiatives of the administration to include the Governor's Health Reform Commission, Virginia Performs and the agency's new performance measures, and the agency's participation in the 2-1-1 initiative. She also informed the Board that the agency would be moving from its current location to the former Circuit City headquarters in Henrico County in July or August 2007 as a result of negotiations with Philip Morris USA which wants to take over this building. The agency will be co-locating with several other state agencies in a negotiated lease expected to provide significant savings over the course of the new lease.

PUBLIC COMMENTS:

No public comments were received at this time.

LEGILATIVE UPDATE:

Ms. Yeatts reviewed legislative actions of the 2007 General Assembly that the Department of Health Professions had been tracking.

UPDATE ON REGULATIONS IN PROCESS:

Ms. Yeatts presented the board with an overview of all ongoing regulation processes

PETITION FOR RULEMAKING-SUTHAR PARESH, CAVALIER PHARMACY ON TELEPHARMACY:

Mr. Paresh requested that the Board consider promulgating regulations to allow a pharmacist in one pharmacy to supervise a pharmacy technician working in a second pharmacy using technology.

The Board did receive one comment in response to this petition for rulemaking from the Virginia Pharmacist's Association (VPhA). VPhA provided the opinion that the current state of technology in Virginia did not support this concept at this time, and that such technology needed to be thoroughly vetted before even a pilot program should be implemented. It also commented that most likely statutory changes would be needed in order to allow telepharmacy as requested in the petition. The comment went on to differentiate between the situation that generated the trial of telepharmacy in North Dakota where there is a significant problem with access to pharmacy services that is not the case in Virginia, and stated the opinion that if the Board decided to consider this, it should do so because such a change was needed as a benefit to citizens of Virginia and their medical needs rather than for business reasons.

The Board discussed the fact that in order to adequately supervise a second pharmacy, the pharmacist at the first pharmacy would need to continuously monitor the technician by some type of visual monitoring device and did not believe that one pharmacist could adequately supervise the first pharmacy and also provide constant

video surveillance of a second pharmacy. The Board had significant concerns about the potential for dispensing errors and patient safety at both locations under this scenario. It also had concerns that the state of current technology had not been proven to be adequate to allow a pharmacy to operate remotely. If the system went down, then a pharmacy technician would have access to a pharmacy unsupervised. This raised concerns about both drug security as well as patient safety. The Board also did not feel that current pharmacy technician competencies were such that a pharmacy technician could safely work without direct, on-site supervision by a pharmacist. Mr. Casway advised the Board that additionally, there are provisions in statute that would need to be addressed before the Board could move forward with regulations. Mr. Brown moved and the Board voted unanimously to deny Mr. Paresh's petition for rule-making.

PETITION FOR RULEMAKING-DONALD BLEVINS ON REQUIREMENTS FOR CONTINUED COMPETENCY FOR PHARMACY TECHNICIANS:

Mr. Blevin requested that the Board consider removing the CE requirement in regulation for pharmacy technicians because currently there is little CE available that is specifically designed for pharmacy technicians. The petition stated that pharmacy technicians currently had access primarily to CE for pharmacists that was too complex for most pharmacy technicians to comprehend. Ms. Russell stated that she had just received communication from ACPE who is revising standards for pharmacy CE providers. By January 2008, CE providers will be required to code all CE programs as to whether the program is content appropriate for pharmacists, pharmacy technicians, or both. This should resolve the problem identified by Mr. Blevins within a year. It was also noted in discussion that there is live CE currently offered specifically for pharmacy technicians by the associations in Virginia, but it was acknowledged that there is not much self-study CE available that meets requirements. Mr. Casway advised that the statute does require the Board to promulgate regulations establishing continuing competency requirements for pharmacy technicians, so he did not think that the Board could completely remove the requirement. Mr. Ross moved and the Board voted unanimously to deny Mr. Blevin's petition for rule-making.

JOHN D. KALVELAGE-REQUEST CONCERNING COMPLIANCE PACKAGING:

Mr. Kalvelage represents a compliance packaging product in which all of a patient's medications for a given time administration are placed in a tear-off blister pack on a card. The card would be labeled with full labeling requirements including patient name, prescriber name, name of drugs and full directions for use for each, and a description of each drug. The individual blisters have the patient name, name of each drug in the blister and the date and time of administration for that blister's contents. Mr. Kalvelage, on behalf of the long-term care facilities that he serves, requested that the facilities be allowed to tear off the appropriate doses and

provide only those doses to patients going away on pass from the facility provided they also provide some other document with the doses that provides any missing labeling information such as the MD name, pharmacy name and phone number. Mr. Stredler moved and the Board voted unanimously to adopt a guidance document in principle to interpret that the tear off doses labeled with the drug name, directions for administration, and each drug name constituted substantial compliance with labeling requirements provided other required labeling information accompanied the torn off blisters.

APPROVAL FOR AN INCREASE IN COST OF THE PHARMACY TECHNICIAN EXAM:

Ms. Russell stated that the contractor responsible for the development and administration of the Board's pharmacy technician examination requested that the Board allow a $10 increase in the cost of the examination from the current cost of $55 to $65. Ms. Russell stated that the contract is eligible for one more annual renewal on February 2, 2007, and that the contract could be amended at this time to include the fee increase. The contractor stated that the examination is not currently supporting itself. Mr. Ross moved and the Board voted unanimously to increase the pharmacy technician examination fee to $65.

INTERPRETATION OF §54.1-3408.01 (A) (i) CONCERNING CHART ORDERS AT OUTPATIENT PHARMACIES

Ms. Russell stated that Board staff frequently receive questions as to whether a chart order written as discharge orders for a patient could be used as a legitimate prescription by a community pharmacy to fill discharge medications, as it contains multiple prescriptions written on one order form. Section 54.1-3408.01 (A) (i) allows multiple prescriptions per blank for chart orders for patients in hospitals. Ms. Russell asked the Board to consider an interpretation of this statute as to whether a discharge order containing multiple prescriptions on one blank, if written when the patient was in a hospital, could then be filled by a community pharmacy. There was a significant amount of discussion as to what actually constituted a chart order for discharge prescriptions versus just a listing of all medications when a patient is discharged, and how a community pharmacist would be able to tell the difference. The Board was amenable to allowing this provided there was sufficient guidance for pharmacists to be able to ensure that they actually had authority to fill from the chart order. Mr. Stredler moved and the Board voted unanimously for staff to draft a guidance document to be presented at the March Board meeting for further discussion.

EXECUTIVE DIRECTOR'S REPORT:

- **RETREAT UPDATE:**

Ms. Russell stated that the retreat would be held on March 28 and the full Board meeting on March 29, but that the retreat would be held here at the Board offices. In reviewing costs of holding the retreat in Williamsburg or another location outside of Richmond, it was determined that it would cost the Board approximately an additional $1500 over the cost of holding it in Richmond because of the cost of having department staff on travel status to include lodging, mileage and meals. She stated that she and Mr. Beckner would be meeting soon to put the agenda together, but that the Board would discuss the issues of drug disposal and dispensing errors, as well as ways to streamline the disciplinary processes to meet the new agency performance standards.

- **REVENUE AND EXPENDITURE ANAYLSIS**

Ms. Russell presented a letter from the Director of DHP stating that the Board's revenues and expenditures were in line and that there is no current need for any fee changes.

- **ACPE REQUEST UACP SITE VISIT:**

Mr. Beckner moved and the Board voted unanimously to have Elizabeth Scott Russell participate with the Accreditation Council for Pharmacy Education (ACPE) site visit to the University of Appalachia College of Pharmacy on April 24-26, 2007, to evaluate the Doctor of Pharmacy program.

- **REPORT ON THE DISCIPLINARY PROGRAM**

Ms. Reiniers-Day gave a report concerning the Board's disciplinary caseload and stated that 271 cases were at enforcement level, 33 at APD level, 46 at the Board level, 12 at informal level and five at formal level.

- **REPORT ON LICENSING, INSPECTIONS, NEWSLETTERS AND THE WEBSITE**

Ms. Juran provided an update on licensure statistics indicating that the Board had issued over 850 additional licenses since the September meeting. This figure included 540 new pharmacy technician registrations. She also reported that the renewal cycle was successful and that over 20,000 licensees had renewed appropriately. Approximately 95% of the pharmacists and pharmacy technicians had renewed online. She then mentioned that she had received the 2006 inspection statistics which indicated that 1,129 inspections had been performed for the Board during 2006. Additionally, she reported that the next newsletter was set for publishing on February 1, 2007. Over 10,000 alert emails were planned to be sent that day alerting licensees of the new publication. Regarding the website, she plans to organize the guidance documents in a more user-friendly manner. Lastly, she mentioned that she had recently presented a continuing education program at the VCU School of Pharmacy and was currently preparing a presentation for the Virginia Pharmacists Association's

mid-year meeting in February 2007.

- **REPORT ON ALL CURRENT PILOT PROGRAMS**

Ms. Juran provided a report on all current and pending pilot programs.

- **REPORT ON THE PRESCRIPTION MONITORING PROGRAM**

Mr. Orr provided 2006 statistics on the prescription monitoring program and gave an update on program activities. There were 1,393,816 records on Jan 1, 2006 and the program ended 2006 with 8,183,138 prescription records. Additionally, 6,333 requests were fulfilled in 2006 compared to 1791 in 2005. Users of the program also increased after the expansion date from 278 registered users at the end of June to 608 users at the end of the year.

Mr. Orr reported that the reporting of dispensing data has improved for in-state pharmacies and dispensing physicians. The program is still having some difficulty with non-resident pharmacy reporting but improvements are starting to be seen in that area also. He updated the Board on the status of providing prescriber notification reports. These are reports to prescribers about their patients that have obtained covered substances from an established number of multiple prescribers and pharmacies within a given time frame. The first set of these reports, over 200 letters, will be sent out February 2, 2007.

CONSENT ORDER PRESENTATION:

Closed Meeting:

Ms. Abernathy moved, and the Board voted unanimously, to enter into closed session pursuant to § 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a consent order. Additionally, she moved that Scotti Russell, Cathy Reiniers-Day, Tiffany Mallory and Howard Casway attend the closed meeting.

Reconvene:

Mr. Stredler moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed meeting.

Mr. Kozera moved, and the Board voted unanimously, to accept the consent order signed by Ronald M. Douglas.

ADJOURN:

With all business concluded, the meeting adjourned at 12:57 p.m.

Elizabeth Scott Russell
Executive Director

John O. Beckner, Board Chair

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF EXAMINATION COMMITTEE

January 31, 2007	Department of Health Professions
Fifth Floor	6603 West Broad Street
Conference Room 2	Richmond, Virginia 23230

A working session of the Examination Committee of the Board of Pharmacy was held at the request of the Board for the purpose of receiving information related to the ExCPT examination and formulating a recommendation for the Board. This meeting started at 1:30PM.

COMMITTEE MEMBERS PRESENT:

Michael Stredler
Jennifer Edwards
Brandon Yi
Gill Abernathy
Elizabeth Scott Russell, Executive Director

STAFF PRESENT:

Caroline Juran, Deputy Executive Director
Howard M. Casway, Assistant Attorney General

PRESENTATION ON THE EXCPT EXAMINATION

Ken Schafermeyer presented information to the committee related to the ExCPT examination. He is seeking to have this examination approved as a second "Board approved" examination for eligibility for applicants for registration as a pharmacy technician. The exam is a two-hour, 100 question examination, with 10 additional pre-test questions, that is similar to the Virginia exam, but longer. The Virginia examination is a 50 question-exam with several questions specifically related to Virginia law. Mr. Schafermeyer had discussed his request with the full board at its September 2006 meeting, but did not have documentation at that time that the test had been determined to have met the standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition). The Board referred this matter to the Examination Committee for a more in-depth discussion and review. Mr. Schafermeyer stated that a letter from Dana Hammer provided to the committee was documentation that the ExCPT exam met the APA standards, however the letter does not say that, and is just a preliminary review, not an actual audit. Mr. Shafermeyer stated that the audit indicates the Virginia exam meets the accreditation standards of the National Commission for Certifying Agencies, which is a higher standard than the APA, that the APA only addresses testing, and that the NCCA contains the APA standards as well as other standards for registration, test site specifications, etc. Ms. Russell explained that even though Mr. Schafermeyer's statements indicate that both exams meet the APA standards, that the Board needs written

documentation specifically stating this, and requested that he provide the Board with this documentation before the Board could consider his request. He stated that he would have Ms. Hammer provide such a letter. There were some additional questions about whether having Ms. Hammer perform the independent audit while appearing on his list of expert panel members for the exam constituted a conflict. Mr. Schafermeyer stated that he hired her to conduct the independent audit and provide advice to the expert committee on psychometrics. He did not consider this a conflict.

DISCUSSION ON CUT SCORE

Mr. Schafermeyer stated that for the Virginia examination, the Board needed to convene a committee to establish an appropriate cut score for the exam forms currently in use. Ms. Russell questioned whether there was a need for additional test forms to be developed. Mr. Schafermeyer stated that there are currently three test forms available and that he has been rotating questions from the item bank on and off test forms based on the exam blueprint. Ms. Russell reminded Mr. Schafermeyer that according to the contract, the Board owns the item bank for the Virginia examination, and that for this reason, the items need to be separate from the items used on the ExCPT examination.

ADJOURN:

With all business concluded, the meeting adjourned at 3:30PM.

Elizabeth Scott Russell
Executive Director

Date

DRAFT/UNAPPROVED (03/07/2007)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR REGULATORY REVIEW

March 7, 2007
Fifth Floor
Conference Room 1

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A working meeting of an ad hoc committee of the Board of Pharmacy for the purpose of conducting a review of regulations was called to order at 9AM.

PRESIDING: John O. Beckner, Chairman

MEMBERS PRESENT: Willie Brown
Michael Stredler
David Kozera
Jennifer Edwards

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst

REVIEW: The committee completed the reviews of Parts VI, VII, VIII, IX, XVI that had not been previously reviewed. It also looked at the recommendations from the previous meeting and made some additional recommendations to some sections. Notes on all recommendations are included in these minutes as Attachment 1

ADJOURN: The meeting was adjourned at approximately 2PM.

Elizabeth Scott Russell
Executive Director

John O. Beckner, Chairman

Date

Part I. General Provisions

18VAC110-20-10. Definitions.

- long term care facility to include other facilities? (NABP rules for institutional pharmacy)
- Definition of CE/CEU- ACPE may be redefining its definition.
- No definition of chart order-needs to be loose enough to include electronic chart orders.
- may want to define what we mean by the term "initial" used in a number of places throughout the regulation, e.g. can this be a stamped set of initials

18 VAC 110-20-15. Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

18VAC110-20-20. Fees.

Part II. Licensure Requirements for Pharmacists

18VAC110-20-30. Requirements for practical experience.

- may just want to identify as possibly inconsistent with new ACPE standards for experiential training, and that NABP is amending model rules. The Board may want to consider amending practical experience requirements to conform to these in order to facilitate reciprocity.
- ACPE standards for preceptors and practical experience may be changing.
- Unclear when first professional year ends.
- ACPE may start allowing practical experience within the first year.

18VAC110-20-40. Procedure for gaining practical experience.

- pharmacists in military hospitals outside the US as preceptors (Tou Yang, Seoul, South Korea
- Does not allow for accepting practical experience outside US.
- Does not allow for pharmacists in military hospital outside the US to serve as preceptors.
- Number of interns that may be supervised may be problematic when schools' programs overlap.

18VAC110-20-50. Curriculum and approved schools of pharmacy.

- (A, 1) is now outdated.

18VAC110-20-60. Content of the examination and grades required; limitation on admittance to examination.

- Does not require applicant to wait a certain time period to take law exam if failed multiple times. Concern is with security of test items for computerized testing.
- Add guidance document 110-39 related to ADA accommodations

18VAC110-20-70. Requirements for foreign-trained applicants.

- clarify that must pass the FPGEE before becoming an intern (staff, and clarification of statute requirements)
- Does not require expiration date on intern licenses.
- No mechanism for extending when good cause shown.

18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.

18VAC110-20-80. Renewal and reinstatement of license.

- (I)- No provision to notify the Board electronically.
- Requirement of annual renewal cycle may be costly or unnecessary.
- #I also needs a time frame instead of "immediately". 14 days was discussed.

18VAC110-20-90. Requirements for continuing education.

- ACPE going to a topic designator system.
- (A)- Date listed is unnecessary.
- (D)- May need to maintain CE for 3 years if Board is going to audit for previous two renewal cycles.

18VAC110-20-100. Approval of continuing education programs.

- Board approved programs do not have expiration dates.
- No mechanism for renewing programs.
- (6)- May need to maintain records for 4 years for auditing purposes.

Part III. Requirements for Pharmacy Technician Registration

18VAC110-20-101. Application for registration as a pharmacy technician.

- Does not include language of 18VAC110-20-111 (C) which allows individual to work for no more than 9 months.

18VAC110-20-102. Criteria for approval for training programs.

- No expiration date assigned to Board approved programs.
- No mechanism for renewing or reviewing programs for law updates, etc.
- No mechanism for submitting changes to programs.
- (C)- does not allow for restricted licensees to serve as instructors.
- Does not require criminal background check.

18VAC110-20-103. Examination.

- Add guidance document 110-39 related to ADA accommodations

18VAC110-20-104. Address of record.

- Thirty day requirement may be too long.
- Does not allow for electronic communication.

18VAC110-20-105. Renewal and reinstatement of registration.

- reactivating vs. reinstatement-statute says 15 hours for each year for reactivating while we have a 60 hour cap on reinstatement. need to change statute or reg.

18VAC110-20-106. Requirements for continued competency.

- (B)- Does not appropriately reference 18VAC110-20-100 in this section, only 18VAC110-20-90.
- D needs to be changed from 2yr to 3 yr to accommodate our audits

Part IV. Pharmacies

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18VAC110-20-110. Pharmacy permits generally.

- Consider adding language about how far from the opening date may a permit be issued.
- not be allowed to operate from a private residence or dwelling
- consider specifying long-standing policy that more than one permit may not be issued to operate out of the same Rx department space to include other types of permits for licenses, e.g. a pharmacy could not also get a second pharmacy permit, or a manufacturer's permit to operate both businesses out of the same physical space.=
- suggestion that instead of immediately returning permit to the board, may want to require that the PIC mark it VOID and the effective date of termination as PIC
- consider not mandating that an outgoing PIC be required to take inventory, but that if they want to the owner has to allow it if the outgoing PIC wants to do one unless there is good cause shown as to why they will not allow it.
- clarify that pharmacy should not share same physical space with another licensed facility
- Add guidance document 110-33 related to pharmacy interns working as pharmacy technicians, here or to 18VAC110-20-111

18VAC110-20-111. Pharmacy technicians.

- requirement for pharmacy to maintain start date & completion date for tech in training
- requirement for techs to post registrations
- (C)- This section is located oddly since A and B reference site specific tech training programs and C references Board approved training programs.
- clarification needed as to whether a PTCB certified pharmacy tech can be unregistered and working as a trainee while enrolled in an approved training program, even though they don't need it.

18VAC110-20-120. Special or limited-use pharmacy permits.

- add free clinic guidance doc 110-22
- look at allowing a community pharmacy serving free clinic to get a second permit

18VAC110-20-121. Innovative program approval.

18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.

- Require closing pharmacy to transfer prescription files somewhere where a patient can access.

18VAC110-20-135. Change of hours in an existing pharmacy.

18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

18VAC110-20-150. Physical standards for all pharmacies.

- (B)- does not include actual effective date of chapter.

18VAC110-20-160. Sanitary conditions.

18VAC110-20-170. Required minimum equipment or resources.

18VAC110-20-180. Security system.

- put effective dates in #5 & 6 (11/4/1993)
- Does not require alarm to be "hard-wired" (this may be problematic based on new wireless technology which utilizes a monitored battery)
- May be problematic to exempt some pharmacies from having an alarm system.
- Require alarm to be monitored.

- #7 want to change to say prior to closing for business instead of within 72 hours

18VAC110-20-190. Prescription department enclosures; access to prescription department.

- (B, 2)- does not require the "other secured place" to be within the pharmacy.
- Clarify #3 & #4 to allow for drop down gates, therefore door with lock would be unnecessary-however, may still want to require a lock for times when pharmacist may not want to pull down gates.

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

- rules for automated will call devices (current pilot)
- storage of will-call, confusion as to whether they have to be in Rx Dept alarmed after hours, reach over a counter and access them (staff)
- may want to clarify the question about medical devices being able to be outside the Rx dept.-similar to paraphernalia.

18VAC110-20-210. Disposal of drugs by pharmacies.

- Identified as being problematic.

Part V. Nuclear Pharmacies

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

18VAC110-20-230. Qualification as a nuclear pharmacist.

Part VI. Drug Inventory And Records

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

- require a perpetual inventory for CII and possibly hydrocodone products, to include a monthly count-back to reconcile count- to be performed at least every 30 days
- Strike #4 (confusing and is only for Board's benefit)
- Clarify storage of records- #3 location may be building where drugs are located.
- Add requirement to maintain CVI invoices.
- Add guidance document 110-35 to include allowance for retail pharmacies to use chart orders

18VAC110-20-250. Automated data processing records of prescriptions.

18VAC110-20-255. Other dispensing records.

18VAC110-20-260. [Repealed]

Part VII. Prescription Order And Dispensing Standards

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

- how paragraph C applies in institutions- primarily about initialing the labels on IV's and maybe first doses, with no permanent record
- Look at ratios (consider open-ended; possibly needs other safety parameters around it)
- 270 E- Add statement to retain knowingly forged prescription (possibly after verifying with prescriber)

18VAC110-20-275. Delivery of dispensed prescriptions.

- require that manual/contract be maintained at both pharmacy and ADS
- Strike "if required by law" in B2h & C2E (obtaining consent, etc)
- Add allowance for tech to serve as responsible party at an alternate delivery site (follow pilot program- see if reg change is needed)
- Possibly beef-up who may have alternate delivery site, as approved by Board (patient compliance/safety versus convenience)

18VAC110-20-276. Central or remote processing.

18VAC110-20-280. Transmission of a prescription order by facsimile machine.
- clarify that hospice can be home hospice
- need to change "nursing home" to LTCF
- clarify if nurse may fax verbal order as prescriber's agent even though not being faxed from prescriber's practice location;(In #4, add or except done by authorized agent in #3)
- Refers 54.1-3408.01 "C"; should be "B".
- Add allowance to fax CIII-VI written prescriptions to pharmacy from a facility such as LTC & establish time requirements to follow-up with hard copy

18VAC110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.
- change definition of agent to 3408.03C not D

18VAC110-20-290. Dispensing of Schedule II drugs.

18VAC110-20-300. [Repealed]

18VAC110-20-310. Partial dispensing of Schedule II prescriptions.

18VAC110-20-320. Refilling of Schedule III through VI prescriptions.
- D- Allow for early refill due to good cause or absence (vacation)
- reword last part of D to clarify that intent is about timing of refill and not about the ability to change Rx based on the strength of drug in stock.

18VAC110-20-321. Compounding.

Part VIII. Labeling and Packaging Standards for Prescriptions

18VAC110-20-330. Labeling of prescription as to content and quantity.
- Add here or possibly create 335- ability to provide alternative labeling/counseling/med guides (possibly include disclaimer to verify with someone else; may need to require both English & other; check with other states)

18VAC110-20-340. Packaging standards for dispensed prescriptions.
- Add guidance document 110-12 to B.
- Add guidance document 110-23.

18VAC110-20-350. Special packaging.
- Repeal entire regulation and rely on statute.

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.
- Add pharmacist's initials to filling record for automated counting devices or dispensers (to C, f to verify process as stated in A)

- Add guidance document 110-16.
- Clean up #4 & change "second" to "subsequent" lots.

Part IX. Standards for Prescription Transactions

18VAC110-20-360. Issuing a copy of a prescription that can be refilled.
- See if #2 is same as DEA. If not, consider striking #2 & #3.

18VAC110-20-370. (Repealed)

18VAC110-20-380. (Repealed)

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.
- Add guidance document 110-20

18VAC110-20-395. Purchase of drugs.
- Clarify to allow for non-licensed warehouse to sell to pharmacy (intra-company sales)

18VAC110-20-400. Returning of drugs and devices.
- Add hospital as referenced in 3411.1

18VAC110-0-410. Permitted physician licensed by the board.
- Add "pharmacy" term to paragraph A.

18VAC110-20-411 through 18VAC110-20-416. (Repealed).

18VAC110-20-417 to 18VAC110-20-419. [Reserved]

Part X. Unit Dose Dispensing Systems

18VAC110-20-420. Unit dose dispensing system.

18VAC110-20-425. Robotic pharmacy systems.
- Does not include 5% pharmacist check allowance as stated in many robot applications.

Part XI. Pharmacy Services to Hospitals

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.
- quantity or duration of order?
- request to add suture kits and anesthesia kits to list of thing that can be stored outside the pharmacy
- (D)- Is unclear if non-pharmacy personnel may be unlicensed personnel.
- Consider requirement of monthly drug review similar to LTC if patient stays longer than 30 days (ex.-acute psych hospitals)

18VAC110-20-450. After-hours access to the pharmacy.
- after-hours access to pharmacy-now in conflict with JCHAO standards, so may want to list as a problem in NOIRA and look to repeal that section. Maybe come up with alternative language for a night cabinet.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.
- pharmacist required to check before leaving the pharmacy (staff)

- manual delivery record may want to allow off-site as well as requiring that it be kept and for 2 years
- may want to want to allow the audit records to be kept somewhere off-site-not in the pharmacy
- Does not require records for Schedule VI, only II-V.

18VAC110-20-470. Emergency room.

18VAC110-20-480. (Repealed)

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

- for 490 (1) track the language in 555 (5) related to requiring a pharmacist to check delivery orders before they leave the pharmacy (staff)
- maintaining record of filling for CVI not addressed
- Does not allow pharmacies to keep records off-site.
- Confusion with 5C as to what a sampling means (all drugs dispensed from each device within 24 hours or all dispensed to a particular pt within 24 hours or all of a drug dispensed within 24 hours)

18VAC110-20-500. Licensed emergency medical services agencies program.

- pharmacist required to check before sealing (staff)
- some ability to do 1:1 exchange without having to have the CSR (various, staff)
- ability to have fluids outside the box (various, staff)
- Does not include similar language regarding methods of sealing box as found in 18VAC110-20-540 and 18VAC110-20-550.
- OEMS had issue with signing by medical pracitioner or the OMD- resolved??

18VAC110-20-510. Identification for medical intern or resident prescription form in hospitals.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

18VAC110-20-520. Drugs in long-term care facilities.

- needs to be moved into Part XII (staff)
- allow stocking of OTC meds (Beverley Group); should prescription be necessary for OTC's

Part XII. Pharmacy Services to Long-Term Care Facilities

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

- limit the number of reviews that may be done by one pharmacist in a day-recommendation not to exceed 75 patient reviews per day (Empsy Munden)
- Does not address possible allowance for dispensing set quantity of drug from discharge orders that do not specify quantity or duration of order.
- Need to reference 210

18VAC110-20-540. Emergency drug kit.

18VAC110-20-550. Stat-drug box.

- change language to allow nurse in assisted living to access even if use med aides - Guidance Doc 110-11(numerous requests including Neighborcare, Virginia Association of Nonprofit Homes for the Aging (VANHA), and Virginia Health Care Association);

- introductory paragraph-the "shall" should be a "may" and I would even say "may only" and change the wording to say nurses rather than persons licensed to administer
- Allowed quantity of doses may be too low.
- Number of drugs per therapeutic class may be too restrictive.
- Does not allow for oral Schedule II drugs which may be problematic.

18VAC110-20-555. Use of automated dispensing devices.

- maintain record of filling CVI?
- in #5 need to require that that record be maintained and for how long, or do a catch all at the end that says something like all records required by this section shall be maintained for 2 years.
- may want to want to allow the audit/delivery records to be kept somewhere off-site-not in the pharmacy
- Does not require records or audits of Schedule VI, only II-V.
- Perhaps look at allowing override capability for emergency meds (at least within hospital with a LTC setting)

18VAC110-20-560. Floor stock.

Part XIII. Other Institutions and Facilities

18VAC110-20-570. Drugs in infirmaries/first aid rooms.

- Strike D
- C,1- Change "chapter" to "section" and add "when written prescription may not be readily obtained"
- Strike "#1" & "#2", but keep statements.
- Change "controlled drug" to "controlled substance"

18VAC110-20-580. Humane societies and animal shelters.

- A,1- add that such record of certification be maintained at facility
- Confusion with "animal shelter"
- Clarify that drugs must be administered at permitted facility (either make new one or put in #3)

18VAC110-20-590. Drugs in correctional institutions.

- allow the use of samples in correctional centers (Colton Hand-pilot) and drugs from places other than pharmacies
- take the definition part out and add it to 10
- Missing letter A.
- Does not define correctional facility.
- Does not allow for the use of other types of forms to accompany returned drugs to the pharmacy- is restricted to drug administration record.
- Allowed number of drugs per therapeutic class and number of doses in stat box and emergency box is too few, especially for alcohol withdrawal in correctional facilities.
- Confusion as to whether correctional health assistants may access stat and emergency boxes or must it be a licensed individual.
- No provision for jails to stock tetanus or vaccines without a controlled substances registration.

Part XIV. Exempted Stimulant or Depressant Drugs and Chemical Preparations

18VAC110-20-600. Excluded substances.

18VAC110-20-610. Exempted chemical preparations.

18VAC110-20-620. Exempted prescription products.

18VAC110-20-621. Exempted anabolic steroid products.

18VAC110-20-622. Excluded veterinary anabolic steroid implant products.

- **Federal regulations will be checked to ensure that these regulations are still consistent**

Part XV. Medical Equipment Suppliers

18VAC110-20-630. Issuance of a permit as a medical equipment supplier.
18VAC110-20-640 through 18VAC110-20-670. (Repealed.)
18VAC110-20-680. Medical equipment suppliers.

Part XVI. Controlled Substances Registration for Other Persons or Entities

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

- **add the requirement for inspection prior to issuance, and require that on any change of location of drug stock or remodeling have to make application and be inspected.**
- **include 14 day requirement and drugs may not be stocked until approved-track language in 140C**

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

- **change in responsible party-have to send in old registration?**
- **Look at current technology re: alarm standards- battery operated alarms (180 & 700)**
- **C- clarify that prescribers, nurses, pharmacists & techs may access controlled substances?? (who may access drugs); clarify that this is defining who may be the responsible party; strike for emergency situation.**
- **#3 clarify that this is defining who may be the supervising practitioner- PA's, NP's not captured.**

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

- **Alarm requirements- battery technology.**

18VAC110-20-720. Requirements for recordkeeping.

18VAC110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.

Virginia Regulatory Town Hall

townhall.state.va.us

Fast Track Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-10-10 et seq.
Regulation title	Public Participation Guidelines
Action title	Periodic review; clarifications
Document preparation date	3/29/07

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The Board has acted to update and clarify its guidelines for public participation in the development and promulgation of initial, amended or repealed regulations, such as inclusion of electronic notification and the Virginia Regulatory Townhall as an option for comment, clarification of certain terms used in the regulation and an extension of the time limitation on ad hoc committees.

Statement of agency final action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On March 29, 2007, the Board of Pharmacy took action to amend 18VA110-10-10 et seq., Public Participation Guidelines, through the fast-track regulatory process.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

The specific statutory mandate for guidelines for public participation in the regulatory process is found in the subsection D of § 2.2- 4007:

§ 2.2-4007. Notice of intended regulatory action; public participation; informational proceedings; effect of noncompliance.

D. Public participation guidelines for soliciting the input of interested parties in the formation and development of its regulations shall be developed, adopted and utilized by each agency pursuant to the provisions of this chapter. The guidelines shall set out any methods for the identification and notification of interested parties, and any specific means of seeking input from interested persons or groups that the agency intends to use in addition to the Notice of Intended Regulatory Action. The guidelines shall set out a general policy for the use of standing or ad hoc advisory panels and consultation with groups and individuals registering interest in working with the agency. Such policy shall address the circumstances in which the agency considers the panels or consultation appropriate and intends to make use of the panels or consultation.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The Board has updated and clarified its guidelines for public participation in the development and promulgation of initial, amended or repealed regulations, such as inclusion of electronic notification and the Virginia Regulatory Townhall as an option for comment. Changes are recommended by a committee of board and/or department staff, which reviewed each regulation for effectiveness, consistency and clarity. The intent is for amendments to be clarifying rather than substantive. Full participation by the public and regulated entities in the regulatory process is necessary to ensure that regulations fulfill the purpose of protecting the health and safety of the public in a manner that is not overly burdensome to those being regulated.

Rationale for using fast track process

Please explain why the fast track process is being used to promulgate this regulation.

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from (1) 10 or more persons, (2) any member of the applicable standing committee of either house of the General Assembly or (3) any member of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The fast-track process is being used to promulgate the amendments because there is general agreement with the changes proposed. The action is not controversial, as it is reflected by the fact that there was no public comment on a Notice of Intended Regulatory Action filed by other boards within the Department of Health Professions. Both the Department of Planning and Budget and the Governor's office have recommended that these amendments be promulgated by a fast-track action.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The regulation has been reviewed for consistency with law, clarity and ease of compliance. There are no substantive amendments.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

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There are no disadvantages to the public of these amendments. Clarification of regulation, additional opportunity for comment, and an extension of service for an ad hoc committee appointed to advise the board on the development of a regulation are all intended to give interested parties more access to the process.

There are no advantages or disadvantages to the agency or the Commonwealth.

There are no other pertinent matters of interest.

Economic impact

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	The agency will incur some one-time costs (less than $1,000) for mailings and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings or distribute notices by email. There are no ongoing expenditures related to this amendment. As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals who may be affected would be persons interested in the regulatory work of the board.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The agency has no estimate of the number of entities that will be affected. Interest in any given regulatory process varies, so the number of entities that may respond will also vary.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There would be no additional costs to the affected entities.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

During its review of the board's public participation guidelines (PPG), staff of the board and the department examined PPG regulations of a number of other state boards and agencies. The purpose was to determine whether there was alternative language that could be adopted that would state the regulations more clearly or whether there were other provisions that would make regulations more effective. Several of the amendments recommended by the review committee were adopted from other such regulations.

The committee also reviewed sections of the Administrative Process Act and the current Executive Order on the promulgation of regulations to ensure that the guidelines were consistent with those requirements.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no potential impact of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes.

Amendments in section 10 on the purpose for the regulations.

An amendment is adopted to specify that the development and promulgation includes the initial formation and development, amendment or repeal of regulations. Cites for the provisions of the Administrative Process Act (APA) of the Code of Virginia throughout the regulations will be updated to reflect the recodification that took place since this chapter was last amended.

Amendments to section 20 on definitions.

The definition for "notification lists" will be amended to refer specifically to the Virginia Regulatory Town Hall and to ensure that notification includes electronic means as well as mailing paper copies.

A new definition for "regulation," consistent with the definition of the APA will be added for clarity since the public often confuses law and regulation.

Amendments to section 40 on documents to be sent to persons on the notification lists.

A requirement that persons on the notification list be sent a notification of the adoption of a final regulation and instructions as to how to obtain a copy of the regulation will be deleted and replaced with a requirement that the board must post notification of the adoption of a final

regulation and copies of the regulation on the board's website prior to the 30-day adoption period.

The board will also include a rule found in the PPG regulations of many other boards or agencies that provides that the failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation otherwise adopted in accordance with this chapter.

Amendments to section 50 on a petition for rulemaking.

An amendment will provide that the board has the sole authority to dispose of the petition to ensure that petition requests would be brought to the board and not reviewed and dismissed by staff or some other entity.

Amendments to section 60 on a notice of intended regulatory action.

The following are added: 1) an introductory sentence to explain the purpose of a notice of intended regulatory action, and 2) the APA requirement for a public hearing if the Governor so directs.

Amendments to section 70 on a notice of comment period.

An introductory sentence to explain the purpose of a notice of comment will be added.

Amendments in section 80 on the notice of meeting.

Amendments are adopted to clarify and update the language of the regulation.

Amendments to section 100 on a periodic review of regulations.

Amendments will be proposed to clarify that the periodic review of regulations should be consistent with the Executive Order of the Governor in accordance with the APA. Other terms will be amended for consistency in the regulation.

Amendments in section 120 on limitation of service.

The board proposes to extend the duration of an ad hoc committee from 12 to 18 months because the development of regulatory language with such a committee often includes discussion of issues prior to adoption and publication of a NOIRA and consideration of comment on the NOIRA and the proposed regulation. Rather than setting in regulation a time of six months for any extension of the committee, the board would be authorized to continue the committee for an additional period of time to complete the specific advisory task for which it appointed.

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Virginia Board of Pharmacy

CHAPTER 10

PUBLIC PARTICIPATION GUIDELINES

Part I

General Provisions

18VAC110-10-10. Purpose.

The purpose of this chapter is to provide guidelines for the involvement of the public in the ~~development and promulgation~~ initial formation and development, amendment or repeal of regulations of the Board of Pharmacy. The guidelines do not apply to regulations exempted or excluded from the provisions of the Administrative Process Act (§~~9-6.14:4.1~~ 2.2-4000 et seq. of the Code of Virginia). These rules seek to expand participation by providing for electronic exchange with the public and thereby increasing participation, reducing costs, and improving the speed of communication.

18VAC110-10-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Administrative Process Act" means Chapter ~~1.1:1~~ 40 (§~~9-6.14:1~~ 2.2-4000 et seq.) of Title ~~9~~ 2.2 of the Code of Virginia.

"Board" means the Board of Pharmacy.

"Notification lists" means lists used by the board to notify persons pursuant to these rules. Such lists may include electronic ~~mailing~~ lists maintained through ~~a state website~~ the Virginia Regulatory Town Hall or ~~regular mailing~~ lists maintained by the board.

"Person" means an individual, a corporation, a partnership, an association, a governmental body, a municipal corporation, or any other legal entity.

"Regulation" means any statement of general application, having the force of law, affecting the rights or conduct of any person, adopted by the board in accordance with the authority conferred on it by applicable laws.

Part II

Notification Lists

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18VAC110-10-30. Composition of notification lists.

A. The board shall maintain lists of persons who have requested to be notified of the initial formation ~~and promulgation~~, development, amendment or repeal of regulations.

B. Any person may request to be placed on a notification list by indicating so electronically or in writing to the board. The board may add to a list any person it believes will serve the purpose of enhancing participation in the regulatory process.

C. The board may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.

D. The board shall periodically request those persons on the notification lists to indicate their desire to either continue to receive documents by regular mail, be notified electronically or be deleted from the lists. Persons who elect to be included on an electronic mailing list may also request that all notices and mailings be sent in hard copy. When either regular or electronic mail is returned as undeliverable or there has been no response to the request from the board, such persons shall be deleted from the list.

18VAC110-10-40. Documents to be sent to persons on the notification lists.

A. Persons on the notification lists, as described in 18VAC110-10-30, shall be mailed or have electronically transmitted the following documents related to the promulgation of regulations:

1. A notice of intended regulatory action.

2. A notice of the comment period on a proposed regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.

~~3. A notification of the adoption of a final regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the board office.~~

4 3. A notice soliciting comment on a final regulation when the regulatory process has been extended.

B. Notification of the adoption of a final regulation and copies of the regulation shall be posted on the board's website prior to the 30-day adoption period.

C. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation otherwise adopted in accordance with this chapter.

Part III

Public Participation Procedures

18VAC110-10-50. Petition for rulemaking.

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A. As provided in §~~9-6.14:7.1~~ 2.2-4007 of the Code of Virginia, any person may petition the board to develop a new regulation or amend an existing regulation.

B. A petition shall include but need not be limited to the following:

1. The petitioner's name, mailing address, telephone number, and, if applicable, the organization represented in the petition.

2. The number and title of the regulation to be addressed.

3. A description of the regulatory problem or need to be addressed.

4. A recommended addition, deletion, or amendment to the regulation.

C. The board shall receive, consider and respond to a petition within 180 days, and shall have the sole authority to dispose of the petition.

D. Nothing herein shall prohibit the board from receiving information from the public and proceeding on its own motion for rulemaking.

18VAC110-10-60. Notice of Intended Regulatory Action.

A. The board shall issue a notice of intended regulatory action (NOIRA) whenever it considers the adoption, amendment or repeal of a regulation. The ~~notice of intended regulatory action (NOIRA)~~ NOIRA shall state the purpose of the action and a brief statement of the need or problem the proposed action will address.

B. The NOIRA shall indicate whether the board intends to hold a public hearing on the proposed regulation after it is published. If the board does not intend to hold a public hearing, it shall state the reason in the NOIRA.

C. If prior to the close of the 30-day comment period on the NOIRA, the board receives a request for a public hearing on the proposed regulation from at least 25 persons or if the Governor directs the board to hold a public hearing, such a hearing shall be scheduled.

18VAC110-10-70. Notice of Comment Period.

A. Prior to the 60-day comment period, the board shall issue a notice of comment period (NOCP) whenever it propose to initiate, amend or repeal a regulation or amend an existing regulation under a fast-track process. The ~~notice of comment period (NOCP)~~ NOCP shall indicate that copies of the proposed regulation are available electronically or from the board and may be requested in writing from the contact person specified in the NOCP.

B. The NOCP shall indicate that copies of the statement of substance, issues, basis, purpose, and estimated impact of the proposed regulation may also be requested in writing.

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C. The NOCP shall make provision for comments pertaining to the proposed regulation by regular mail, ~~Internet,~~ facsimile or electronic means. With the exception of comment received at a scheduled public hearing, oral comment ~~may~~ shall not be accepted.

18VAC110-10-80. Notice of meeting.

A. At any meeting of the board or advisory committee at which the formation, amendment, repeal, or adoption of a regulation is anticipated, the subject shall be described in a notice of meeting, which has been posted electronically on the ~~Internet~~ Virginia Regulatory Town Hall and transmitted to the Registrar of Regulations for inclusion in the Virginia Register.

B. If the board anticipates action on a regulation for which an exemption to the Administrative Process Act is claimed under §~~9-6.14:4.1~~ 2.2-4002 or §2.2-4011 of the Code of Virginia, the notice of meeting shall indicate that a copy of the proposed regulation ~~is available on a state website or upon request to~~ may be requested from the board at least two days prior to the meeting. A copy of the regulation shall be made available to the public attending such meeting.

18VAC110-10-90. Public hearings on regulations.

The board shall conduct a public hearing during the 60-day comment period following the publication of a proposed regulation or amendment to an existing regulation unless, at a noticed meeting, the board determines that a hearing is not required.

18VAC110-10-100. Periodic review of regulations.

A. ~~Unless otherwise directed by executive order,~~ The board shall conduct ~~an informational proceeding~~ a periodic review of its regulations ~~at least every two years~~ consistent with an executive order issued by the Governor and with § 2.2-4007.1 of the Code of Virginia to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance.

B. Such ~~proceeding~~ review may be conducted separately or in conjunction with other ~~informational proceedings~~ meetings or hearings.

C. Notice of the proceeding shall be transmitted to the Registrar of Regulations for inclusion in the Virginia Register and shall be sent to the ~~mailing list~~ notification lists identified in 18VAC110-10-30.

Part IV

~~Advisory~~ Ad Hoc Committees

18VAC110-10-110. Appointment of committees.

A. The board may appoint an ad hoc ~~advisory~~ committee whose responsibility shall be to assist in the review and development of regulations for the board.

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B. The board may appoint an ad hoc ~~advisory~~ committee to provide professional specialization or technical assistance when the board determines that such expertise is necessary to address a specific regulatory issue or need or when groups of individuals register an interest in working with the agency.

18VAC110-10-120. Limitation of service.

A. An ~~advisory~~ ad hoc committee which has been appointed by the board may be dissolved by the board when:

1. There is no response to the Notice of Intended Regulatory Action, or

2. The board determines that the promulgation of the regulation is either exempt or excluded from the requirements of the Administrative Process Act ~~(§9-6.14:4.1 of the Code of Virginia)~~.

B. An ~~advisory~~ ad hoc committee shall remain in existence no longer than ~~12~~ 18 months from its initial appointment unless ~~1. If~~ the board determines that the specific regulatory need continues to exist beyond that time~~, it shall set a specific term for the committee of not more than six additional months~~. The board may authorize the ad hoc committee to continue for an additional specified period of time to complete the task for which it was appointed.

~~2. At the end of that extended term, the board shall evaluate the continued need and may continue the committee for additional six-month terms.~~

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COMMONWEALTH of VIRGINIA
Office of the Attorney General

Robert F. McDonnell
Attorney General

900 East Main Street
Richmond, Virginia 23219
804 - 786 - 2071
804 - 371 – 8946 TDD

March 29, 2007

Elizabeth Scott Russell
Executive Director
Virginia Board of Pharmacy
6603 West Broad Street
Richmond, VA 23230-1717

RE: Proposed Fast-track Regulations
18 VAC110-10-10 et seq. Public Participation Guidelines

Dear Ms. Russell:

I have reviewed the Proposed Fast-track Regulations, as cited above, in accordance with the Administrative Process Act. The amended regulation to update and clarify public participation guidelines is constitutional and in conformity with statutory provisions.

Sincerely,

Senior Assistant Attorney General

c: Elaine J. Yeatts, Agency Regulatory Coordinator
Department of Health Professions

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Background for amendment of guidance document 110-35 for chart order use in outpatient pharmacies.

INTERPRETATION OF §54.1-3408.01 (A) (i) CONCERNING CHART ORDERS AT OUTPATIENT PHARMACIES

Ms. Russell stated that Board staff frequently receive questions as to whether a chart order written as discharge orders for a patient could be used as a legitimate prescription by a community pharmacy to fill discharge medications, as it contains multiple prescriptions written on one order form. Section 54.1-3408.01 (A) (i) allows multiple prescriptions per blank for chart orders for patients in hospitals. Ms. Russell asked the Board to consider an interpretation of this statute as to whether a discharge order containing multiple prescriptions on one blank, if written when the patient was in a hospital, could then be filled by a community pharmacy. There was a significant amount of discussion as to what actually constituted a chart order for discharge prescriptions versus just a listing of all medications when a patient is discharged, and how a community pharmacist would be able to tell the difference. The Board was amenable to allowing this provided there was sufficient guidance for pharmacists to be able to ensure that they actually had authority to fill from the chart order. Mr. Stredler moved and the Board voted unanimously for staff to draft a guidance document to be presented at the March Board meeting for further discussion.

VIRGINIA PRESCRIPTION BLANK REQUIREMENTS

Written Prescriptions:

- Written prescriptions shall be legibly written with ink or individually typed or printed. Prescriptions for Schedule VI drugs may be preprinted with the drug name, directions for use, quantity. Preprinted prescriptions may contain a list of drugs with a checkbox beside the drug name to be selected by the prescriber, but only one drug may be selected for each prescription.

- Written prescriptions shall include the patient's first and last name. Patient address may be entered on the prescription either by the prescriber or agent, or recorded by the pharmacist on the prescription or in an electronic prescription dispensing record system.

- The prescription shall contain the prescriber's name, address, and telephone number, and DEA number if for a Schedule II-V prescriptions. Interns and residents in a residency program may use the hospital DEA number and an assigned suffix. Nurse practitioners' prescriptions shall also include their 10 digit Virginia prescriptive authority number and physician assistants' prescriptions shall include the names of both the physician assistant and the supervising physician.

- Prescriber information shall be either preprinted on the blank, electronically printed, typed, stamped, or printed by hand in a legible manner.

- There is no longer a specific format required for written prescriptions. A pharmacist may substitute an orange-book rated generic product for a brand name drug unless the prescriber prohibits substitution by indicating "brand medically necessary." Until July 1, 2006, prescribers may continue to use the old two-check-box format blanks and prohibit substitution by checking the "Dispense as Written" box. Until July 1, 2006, failure to check either box, or checking the Virginia Voluntary Formulary box allows the pharmacist to substitute any orange-book rated generic. After July 1, 2006, the DAW box checked will not prevent substitution.

- A prescription blank may only contain one prescription. There are a few limited exceptions to this law such as multiple blanks for the Department of Corrections and chart orders for hospital, nursing home, home infusion, and hospice patients. A chart order may be filled by an outpatient (community/retail) pharmacy for outpatient use provided the following conditions are met:

    - The chart order was written while a patient was in the hospital or long term care facility.
    - The pharmacist has enough information to constitute a valid outpatient prescription to include required information as listed in this document for written prescriptions.
    - The pharmacist in an outpatient setting must have enough direction either written or obtained verbally to know that the chart order list of drugs is actually intended to be outpatient or discharge prescription orders, and not merely a listing of drugs the patient was taking while an inpatient.

- The orders include some direction related to quantity to be dispensed or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.

- Written prescriptions may be prepared by an agent for the prescriber's signature, but shall be hand-signed by the prescriber.

- Written prescriptions shall be dated with the date the prescription is written.

- Schedule II prescriptions shall be written and may not be refilled.

Oral Prescriptions:

- Oral prescriptions shall contain all the same information as written prescriptions except for the prescriber's signature, and shall be reduced to writing by the pharmacist receiving the prescription.

- The prescriber or his authorized agent may transmit the prescription. If transmitted by an authorized agent, the pharmacist shall record the full name of the agent. An authorized agent may only be an employee of the prescriber under his immediate and personal supervision, or if not an employee may only be someone who holds a license to administer drugs, such as a nurse, physician assistant, or another pharmacist.

Faxed Prescriptions:

- A faxed prescription is one that starts out as a written prescription, therefore has to meet all requirements for a written prescription, including a manual signature, is placed onto a fax machine in the prescriber's office and sent via phone to a pharmacy's fax machine where a facsimile image is printed for the pharmacy records.

- Schedule III-VI prescriptions may be faxed to a pharmacy.

- Schedule II prescriptions (or chart orders) may **only** be faxed to a pharmacy for long term care facility patients, home infusion patients, and hospice patients.

- Pharmacies may not begin the dispensing process when a prescription is faxed directly from the patient, even if the patient brings in the hard copy when they come to pick up the medication. Prescriptions may only be faxed from the prescriber's practice location

Electronically transmitted prescriptions:

- An electronically transmitted prescription is one that is generated from the prescriber's office electronically, sent out as an electronic transmission, is normally routed through a switch to the appropriate pharmacy, and is received by the pharmacy in the form of an electronic

transmission or is converted by the switch to a fax, and is printed out on the pharmacy's fax machine. An electronically transmitted prescription does not have a manual signature, but would contain an electronic or digital signature of the prescriber. If the prescription is generated electronically, but then is printed out in the office and given to the patient, it is no longer an electronic transmission and must follow the guidelines of a written prescription including a manual signature.

- Schedule VI prescriptions may now be transmitted electronically.

- DEA has not promulgated regulations that authorize the transmission of Schedule II-V prescriptions electronically. For Schedule III-V prescriptions, DEA considers an electronic transmission an oral prescription and the pharmacist must verify the validity by phone contact.

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Background on draft guidance document for non-resident wholesale distributors:

Board staff is getting inundated with requests to write individual letters to various out-of-state entities. The entities are stating that they do not physically possess or distribute any prescription drugs into Virginia, but they may be the manufacturer, or they may hold the NDA even though they do not actually manufacturer or distribute any product, or they may only distribute through another wholesale distributor, or they may be the repackager listed with FDA, but they contract out the repackaging and never handle the product.

This onslaught of such requests may have to do with Florida pedigree requirements, but Board staff does not have the time to respond to these individual requests. Additionally, these entities are not currently registered and staff is relying on their own statements to write a letter telling them they do not have to be. If we could write a simple guidance document and put it on the website, we could refer these requests to the website for an official response.

We may have to amend the draft guidance document statement, as time goes on and scenarios develop that may have a different twist.

draft guidance document 110 - 7

Entities who do not need to register as a Non-resident Wholesale Distributor

An entity located outside Virginia that does not physically possess and ship prescription drugs into Virginia does not need to register with the Virginia Board of Pharmacy as a non-resident wholesale distributor. If, for example, a manufacturer or distributor uses a third-party to physically house and distribute prescription drugs into Virginia, that third-party is required to hold the non-resident wholesale distributor registration and that party's name must be on any invoice as the distributor.

Draft guidance document

Substituting albuterol HFA inhalers for albuterol CFC inhalers

The U. S. Food and Drug Administration (FDA) has published final rules to amend its regulation (21 CFR 2.125) on the use of ozone-depleting substances (ODSs) in medical products. This rule states that as of December 31, 2008, production and sale of single ingredient albuterol CFC metered-dose inhalers (MDI) must cease. Please refer to the FDA website for additional information about this regulation and also information about some differences in inactive ingredients in the formulations that translate primarily into differences in taste and feel. http://www.fda.gov/cder/mdi/mdifaqs.htm

If a pharmacy has a prescription with valid refills for an albuterol MDI that has been previously filled with a CFC product, and the prescriber did not specify CFC on the prescription, a pharmacist may substitute an albuterol HFA MDI for remaining refills without seeking permission of the prescriber, provided the pharmacist specifically counsel the patient about the change to include the reason for the change and differences that he patient may experience.

Russell, Scotti

From: JALeming@aol.com
Sent: Monday, February 26, 2007 2:41 PM
To: Russell, Scotti
Cc: Casway, Howard (OAG); Mallory, Tiffany N.; Becky@vapharmacy.org; Juran, Caroline; ogburn95@comcast.net; chosinging@hotmail.com; a_diggs@hotmail.com; bwebbpcfp@verizon.net; RHamrick@Paraccess.com; Robertscall@aol.com; mjurgensen@msv.org; Harp, William L.; ramdirector@ramdocs.org
Subject: Re: In Re: Mandatory Re-Write of Albuterol Inhaler Scripts

In a message dated 2/26/2007 1:47:44 PM Eastern Standard Time, Scotti.Russell@DHP.VIRGINIA.GOV writes:

> Hello, Joe.
>
> This is going to be an issue, and I agree with you that everyone would be best served by allowing the substitution. I will forward your email to Howard Casway for his thoughts. The problem is not in regulation, but in statute, so rulemaking would not help. It is too bad that the GA is just over this year, because the fastest way to have resolved this may have been through legislation. The Board next meets March 29, and we could put this issue on the agenda, and try to figure out a fix, maybe by way of a guidance document.
>
> My initial thought, without doing any research, is that even though the old CFC is not technically equivalent with the HFA, I would guess that most prescribers have simply written the prescriptions as albuterol (or possibly a brand name like Proventil) without designating a specific propellant (since there used to be only the CFC). If this is the case, then substitution may not really be a problem. For example if you write a prescription by the generic name, then a pharmacist may dispense any generic product on the market whether or not the product is listed by FDA as bioequivalent to an innovator product. In that same vein, I don't see why a prescription simply written for albuterol (inhalation) couldn't be filled with any albuterol for inhalation product on the market. Even if the original prescription was written for a brand name like Proventil, I doubt the propellant was specified. Again, I need to do some research on this before the Board meeting.
>
> Scotti
>
> Elizabeth Scott (Scotti) Russell
> Executive Director, Virginia Board of Pharmacy
> 6603 West Broad Street, 5th floor
> Richmond, VA 23230
> (804) 662-9911
> (804) 662-9313 Fax
> scotti.russell@dhp.virginia.gov
> www.dhp.virginia.gov/pharmacy
>
> ---
>
> **From:** JALeming@aol.com [mailto:JALeming@aol.com]
> **Sent:** Monday, February 26, 2007 1:18 PM
> **To:** Russell, Scotti
> **Cc:** ogburn95@comcast.net; chosinging@hotmail.com; a_diggs@hotmail.com; saundersmann@comcast.net; andogirls@msn.com; bwebbpcfp@verizon.net; RHamrick@Paraccess.com; Robertscall@aol.com; ramdirector@ramdocs.org; mjurgensen@msv.org; pkitchen@msv.org; becky@vapharmacy.org
> **Subject:** In Re: Mandatory Re-Write of Albuterol Inhaler Scripts
>
> February 26, 2007
>
> Dear Ms. Russell (Scotti):

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As you are likely aware -- the (Federal) rules regarding pressurized containers with CFC's as propellant are now set and CFC devices are no longer being made.

Specifically in our market -- some of the Pharmacies are already out of generic Albuterol MDI's.

I am told that Albuterol CFC is not "bioequalivent" with Albuterol HFA.

As such each and every patient in Virginia with a CFC inhaler will be required to have a new prescription issued for the HFA inhaler.

First, and foremost I am concerned about the patient's who wait until they actually need their rescue inhaler, find that inhaler to be empty, try to get another CFC rescue inhaler from the pharmacy and are not able to get an additional inhaler (even with remaining refills on their prescription.)

These patients may suffer dire consequences as a direct and proximate result of this regulatory requirement.

Second, I am concerned that dispensing pharmacists are already too busy and the addition of changing each and ever rescue CFC inhaler out by way of a new prescription may be simply overwhelming.

Lastly, I am concerned that these new prescriptions have a real cost associated with their re-issuance. There is no reimbursement for this cost.

Therefore, I am asking you as the ED of the Virginia Board of Pharmacy if it is within the VBOP's jurisdiction to waive the requirement that a new prescription be issued for a HFA variety of an existing CFC product.

If it is within the ability of the VBOP I respectfully ask that this be accepted as a petition for rule making.

I am told that the final supply of CFC inhalers will likely run out completely in Virginia in September (or thereabouts.)

My question to you and my (proffered) petition for rule making are designed to avert this looming crisis.

Thank you as always for considering my input. With warm personal regards I remain,

Yours in service,

Joe

Joseph Atkins *"Joe"* Leming, MD, FAAFP
Chairman,
Board of Supervisors
Prince George County Virginia
Elected From The First Election District
Serving All Citizens Of The County Of Prince George
(804) 526-4859 (Constituent)
(804) 861-6144 (Home)
(804) 305-5105 (Mobile)
(804) 861-7074 (Pager)
Please visit me and communicate with me through my website @ http://www.joeleming.com/

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February 26, 2007

3/16/2007

Dear Ms. Russell (Scotti):

Good ideas simply cannot go unpunished. I never considered the GA. Go figure that I would write you the Monday after the session closed.

On the other hand - I can with confidence tell you that I have never written a prescription for an inhaled broncho-dilator specifying "a CFC" device. What I have done recently is to write the scripts as HFA's however.

Your approach - by way of a guidance document (perhaps even in concert with the VBOM) seems at first blush very reasonable.

I guess in that scenario - the VBOP (with or without the VBOM) would develop a guidance document that would in essence allow any prescription for an inhaled bronchodilator not specified as CFC to be dispensed as an HFA (which would include virtually all the scripts.)

Please mull it over with Mr. Casway (and PS - please give him my regards.)

Thank you for your thoughtful consideration and creativity. I remain,

Yours in service,

Joe

Joseph Atkins *"Joe"* Leming, MD, FAAFP
Prime Care Family Practice, PC
241 Charles H. Dimmock Parkway, Suite 6
Colonial Heights, Virginia 23834
(804) 526-1111 (Office)
(804) 526-4859 (Direct)
(804) 305-5105 (Mobile)
(804) 861-7074 (Pager)
Please visit me and communicate with me through my website @ http://www.joeleming.com/

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Background for request for approval of ExCPT examination for registration as a pharmacy technician

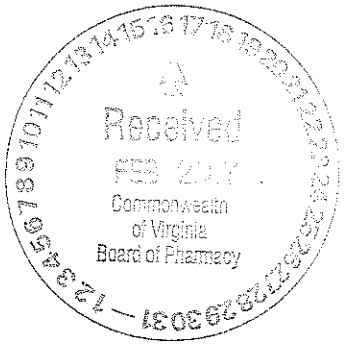
See Draft Minutes of Examination Committee in agenda package on pages 8-9

ExCPT examination is a 2 hour examination developed by the same individual who is the Board's contractor for its approved examination, and is a certification examination being offered nationally as an alternative to PTCB. The Examination Committee reviewed documents presented by Ken Schafermeyer at its last meeting and made no formal recommendation, but had an unanswered question as to whether the examination met the APA standards for testing as required in Board regulations. Staff should have some additional information concerning this issue by the Board meeting.

SCHOOL OF PHARMACY
DEPARTMENT OF PHARMACY

UNIVERSITY OF WASHINGTON

February 11, 2007



Elizabeth Scott Russell, RPh
Executive Director, Virginia Board of Pharmacy
6603 W Broad St, 5th Floor
Richmond, VA 23230-1712

Dear Ms. Russell:

I am writing to provide a brief comparison of certification testing standards between the *Standards for Educational and Psychological Testing* (compiled by the American Educational Research Association [AERA], the American Psychological Association [APA], and the National Council on Educational Measurement [NCME] – commonly referred to as APA Standards) and the *Standards for Accreditation of Certification Programs* from the National Commission for Certifying Agencies (NCCA). The Virginia Exam and the ExCPT are currently using the set of NCCA standards as a guide for its pharmacy technician certification process. It is using this organization because NCCA is known to be the "gold standard" for organizations who want to voluntarily have their programs independently reviewed for quality. There is a statement on the National Organization for Competency Assurance (NOCA) website that says "*NCCA's Standards* exceed the requirements set forth by the American Psychological Association and the U.S. Equal Employment Opportunity Commission." (http://www.noca.org/ncca/ncca.htm, accessed Feb. 7, 2007). NCCA is the accrediting body of NOCA.

The primary difference between NCCA and APA standards is the breadth and scope: NCCA standards apply to the entire certification process, while APA standards apply only to test construction and administration. NCCA standards encompass the essence of APA standards, and are more direct and appropriate for examinations like the Virginia Exam and ExCPT.

Lastly, as an independent auditor for ExCPT, I participated in a one-day workshop with the expert panel as an independent psychometric consultant to provide expert oversight for the process. This is similar to how a CPA might provide independent expert oversight for a corporation. I have no financial interest in, nor am I on the payroll of any organization that provides testing or training of pharmacy technicians.

Please do not hesitate to contact me with any questions.

Sincerely,

Dana Hammer

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Dana P. Hammer
Director, Bracken Pharmaceutical Care Learning Center and Teaching Certificate Program in Pharmacy Education

H-375 Health Sciences Center Box 357630 Seattle, Washington 98195-7630
VM 206.543.6788 FAX 206.543.3835

background for agenda item-Merck request not to provide SSN:

required by 18VAC110-50-70:

18VAC110-50-70. Minimum required information.

A. The application form for a new license or for registration as a non-resident wholesale distributor, or any change of ownership shall include at least the following information:

...

4. The type of ownership and name(s) of the owner of the entity, including:

a. If an individual: the name, address, social security number or control number;

b. If a partnership: the name, address, and social security number or control number of each partner, and the name of the partnership and federal employer identification number;

c. If a corporation:

(1) The name and address of the corporation, federal employer identification number, state of incorporation, the name and address of the resident agent of the corporation;

(2) The name, address, social security number or control number, and title of each corporate officer and director;

(3) For non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent or more of the outstanding stock of the corporation.

(4) The name, federal employer identification number, and state of incorporation of the parent company.

...

required by 54.1-116:

§ 54.1-116. Applicants to include social security numbers, or other identifying number; exemption.

A. Every applicant for a license, certificate, registration or other authorization to engage in a business, trade, profession or occupation issued by the Commonwealth pursuant to this title, and every applicant for renewal thereof, shall provide on the application either his social security number or control number issued by the Department of Motor Vehicles pursuant to § 46.2-342. An initial application or renewal application which does not include either identifying number shall not be considered or acted upon by the issuing entity, and no refund of any fees paid with the application shall be granted.

B. Notwithstanding the provisions of subsection A, a health regulatory board of the Department of Health Professions may issue a temporary license or authorization to practice, effective for not longer than 90 days, to an otherwise qualified applicant for a license, certificate or registration who is a foreign national and cannot provide a social security number or control number at the time of application.

COJ - 3115107

Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004

MERCK
Manufacturing Division

March 12, 2007

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS
6603 WEST BROAD STREET, 5TH FL
RICHMOND, VA 23230-1712

RE: MERCK & CO., INC.; WEST POINT, PA, RENO, NV, DULUTH, GA

To Whom It May Concern:

Respectfully, I am submitted this written request to your Board for review. Per correspondence that has transpired between myself and Caroline Juran, Deputy Executive Director, I understand that this is the procedure for having an agenda item added for your next full Board Meeting.

I have attached a copy of Ms. Juran's letter to my office, which will amply supply the details needed to understand my company's dilemma. We are apprehensive about disclosing our Board of Director's very personal information as requested. We have supplied a notarized Affidavit from our Global Security Department to explain our unease, and it has been rejected. I have enclosed an identical one for your review and files.

We are applying for a Distributor's permit to ship/distribute drugs into your State. I wanted to broach the subject this way first, but if deemed appropriate, I can call on our Legal Department to supply additional reasons surrounding our resistance. From a legal stand point I'm sure they would better answer your inquiries.

Please contact me directly should you have further questions/comments. My number is 215-652-8728.

Thank you for your consideration.

Sincerely,

Melissa M. Creciun

Melissa M. Creciun
Distribution & Logistics

Enclosures

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COMMONWEALTH of VIRGINIA

Sandra Whitley Ryals
Director

Department of Health Professions
6603 West Broad Street, 5th Floor
Richmond, Virginia 23230-1712

www.dhp.virginia.gov
TEL (804) 662 9900
FAX (804) 662 9943
TDD (804) 662 7197

March 9, 2007

Melissa M. Creciun
Distribution and Logistics Department
Merck & Co., Inc.
770 Sumneytown Pike
West Point, PA 19486

Dear Ms. Creciun:

The Board has received and reviewed the information dated February 19, 2007 that you submitted in response to the Board's letter dated February 2, 2007 requesting more information to complete the requirements for the non-resident wholesale distributor permit for the facility located at 4990 Air Center Circle, Reno, NV. The two remaining and unresolved issues consist of the required submission of the social security numbers for each corporate officer, director and responsible party; and the submission of a criminal history record check through the Central Criminal Records Exchange for the responsible party.

First, regarding the concern for providing the social security numbers the Board has reviewed the affidavit signed by Robert D. Moore, Executive Director for Global Security Group, and understands the identified concerns. However, social security numbers are required in Virginia statute §54.1-116 for all applications submitted to the Board. It is, also, specifically required in Board regulation 18VAC110-50-70 for non-resident wholesale distributor applications. Therefore, this information will be necessary to complete your application. Please note, however, that information provided on an application is not subject to disclosure under the Freedom of Information Act and therefore, will not be shared with any outside sources. While this understanding should ease the concerns for submitting social security numbers, should Merck continue to not wish to supply this information a request may be submitted for this issue to be reviewed at the next full Board meeting. The next scheduled meeting is March 29, 2007 and a request for inclusion on the agenda should be made in writing by March 14, 2007.

Secondly, it was noted on the document dated February 19, 2007 that the required background check referenced in our letter dated February 2, 2007 was for employees working solely with the elderly or the disabled public. Therefore, no criminal background history was submitted. The SP167 form referenced in the earlier correspondence, however, is the correct

form for initiating this criminal background report and is not solely used for employees working with the elderly or the disabled public. Therefore, please complete the aforementioned form and submit to the Central Criminal Records Exchange. Please note that you should not use this agency's address for the mail reply field. The responsible party as identified on the non-resident wholesale distributor application must sign the form as the person making the request. Once the completed background history is obtained, please forward to the Board for inclusion with the non-resident wholesale distributor application.

Should you have any questions, you may contact me at (804) 662-9911.

Sincerely,

Caroline D. Juran
Deputy Executive Director
Board of Pharmacy

AFFIDAVIT

Robert D. Moore, being duly sworn, deposes and says:

I am the Executive Director of Global Security for Merck & Corp., Inc.; a New Jersey based pharmaceutical company with worldwide operations. I have been a Corporate Security professional for the past twenty-five years and prior to my career in the private sector worked for the Federal Bureau of Investigation. One of my responsibilities is management of Merck's Executive Protection Program.

The executives specifically included in this program are company Officers, Directors and other key employees who may be the target of activist, extremists, criminal kidnapping groups, etc. One of the important principles of any executive protection is maintaining confidentiality of personal details which, if accessed, could be misused by groups or individuals intent on targeting high profile business executives.

Merck's worldwide headquarters located in Whitehouse Station, NJ and other principal offices around the world are designed to protect our employees against intruders and other security related threats. Special efforts are made to provide a higher level of security for senior executives of the company due to their public profiles resulting from their positions with the company. We carefully restrict information regarding our senior executives travel schedules, itineraries, etc. Additional active measures include home alarm systems and security support including protective details when traveling, as appropriate.

From my discussions with other Heads of Security at U.S. based multinational companies, Merck's Executive Protection is in general alignment with those companies' programs. I strongly believe, as do other senior security executives, that disclosure of residential addresses, social security numbers and any other personal data should not be required in the interests of executive's personal safety and security. Public law enforcement authorities also support this position. Accordingly, I respectfully request that such personal details of Merck & Co., Inc. executives not be required.

Robert D. Moore
Executive Director
Global Security Group

Sworn to before me this
14th Day of July, 2006

Notary

LINDA J. BARAN
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES NOV. 5, 2007

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MEMO

To: File

From: Caroline D. Juran, Deputy Executive Director

Date: 3/21/07

Re: Merck & Co., Inc.; West Point, PA, Reno, NV, Duluth, GA

I left a voicemail with Melissa Creciun today stating that the issue surrounding the submission of social security numbers on non-resident wholesale distributor applications will be added to the Full Board Meeting's Agenda. I informed her that a representative from Merck could choose to attend this meeting, but that it is not required. Additionally, I stated that I would communicate the outcome of the meeting to her as soon as possible. The meeting is scheduled for 3/29/07.

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Background Document concerning Dialysis Centers:

There is a non-resident pharmacy associated with approximately 53 dialysis centers located in Virginia. This pharmacy would like to be able to offer the dialysis patients seen at these centers the option of having all prescription medications, not just dialysis supplies, dispensed by them and delivered to them at the dialysis center for pickup when they come for dialysis (at least three days a week).

Possible Benefits: Convenience for the patients. The pharmacy could certainly mail directly to the patient's homes, but they claim that the security and integrity of the drugs would be compromised by mailing to the patient's homes.

Concerns: The Board has not typically allowed places with no prescriber on site to act as alternate delivery locations unless they were government locations. The concern is that with any alternate delivery site, there is a potential for diversion and errors occurring with the wrong patient getting the wrong medications. Dialysis centers usually have at least one nurse on site, who oversees dialysis technicians who perform the dialysis. The nurse will administer any needed prescription medications with the exception of the few things the dialysis technician is authorized to administer. A prescriber comes into each site occasionally, but is not present the entire time the center is operational, Mon. through Sat.

It would certainly make some sense for the Board to allow items such as Epogen which is dispensed to a patient for administration at a center to be mailed to the center, but this pharmacy wants to be the primary pharmacy for all the patient's medications and mail them all to the centers for pick-up. The argument was made that one pharmacy dispensing all the patient's medications can more effectively monitor this fragile patient by screening for interactions, dosing, compliance, etc. However, the argument can be made that they can still do this as a service of the dialysis program without actually dispensing all the patient's medications, or delivering them all to the dialysis center. It would certainly be more cost effective for the pharmacy to handle the medications using the alternate delivery site than mailing to each individual patient's residence.

Background for new pharmacies and inspection date/issue permit date vs. anticipated opening date:

Recently Board staff have been made aware of a growing problem with some new pharmacy applications. Some applications are requesting an opening inspection date anywhere from 6 weeks to 2 months prior to the anticipated opening date. Most of these that have been identified are larger type operations such as pharmacies located in grocery stores. The reasons identified for requesting this kind of lead time are delays by DEA in obtaining the DEA registration and Schedule II order forms, delays in obtaining the NABP (NCPDP) number for processing claims (although I don't know how the upcoming NPI shift will affect this process), and recently some insurance issues (don't have a lot of information on this last one, but may be the Board meeting). However, staff is not sure that in general these reasons are valid. Most pharmacies already have paperwork into NABP and NCPDP in advance and just need to provide documentation that the pharmacy permit has been issued, and the number which they can get the day the permit is issued. DEA maintains that it issues registrations within two weeks at the most of the state license being issued. We have recent evidence of DEA issuing a registration even in advance of the state issuing and have had several discussions with DEA about this. Staff believes that somewhere around a two-week maximum delay between issuing the permit and the pharmacy opening is reasonable. The Board and inspection staff are very responsive to requests for inspection and typically can issue a permit the same day a pharmacy is inspected provided there are no major deficiencies, which with pharmacies, there usually are not. Most minor inspections are corrected that day and the permit is issued. There are a number of concerns with issuing a permit far in advance of opening. However, because this appears to be a growing issue, the Board should establish policy.

Concerns:
The major concern is that once a permit is issued, a pharmacy can order and stock prescription drugs and with the DEA registration issued, can order and stock Schedule II-V controlled substances. This stock of drugs could sit in an empty, non-operating prescription department with no pharmacist oversight for several months or longer without some policy to restrict lead time for issuance. This would appear to provide a major opportunity for diversion, even with a locked and presumably operational alarm. In most cases, there would be construction workers still in the vicinity of the prescription department and no one responsible for ensuring that the alarm stays on and the drugs stay secure. Even though on opening inspections we ensure that locks and alarms meet standards, there have certainly been a number of occasions where on subsequent inspections, locks are not working, keys lost, alarms not functional or not being used.

some arguments to not issue too early:

- Even though there is PIC listed on the application, the PIC is not in full and actual practice at the location if it is not even open for business for 1 to 2 months.

- This is no different than our requirement that once a pharmacy closes business the drug stock must be removed within 14 days or DHP seizes it. We had the seizure requirement put in law because we didn't want a stock of drugs sitting in a location without a pharmacist oversight. I actually think this is worse than a closing because you have a lot of non-pharmacy related traffic in the area every day whereas in a closed operation, no one is normally coming in.

- They may have an alarm functional and proper security at the time of inspection and the Rx department may meet requirements, when construction is going on all around, things can happen and it may not still meet requirements after 6 weeks. Phone lines to the pharmacy could be inadvertently be cut. Someone with the company, not in the pharmacy loop, could find out they are paying alarm costs, and ask that the alarm be cut off because the pharmacy is not open. Any number of things could happen and go undetected for a long time with not pharmacist oversight.

- Regulations require that the entire area bearing the name of a pharmacy, shall be clean and sanitary, etc. If the rest of the grocery store, big box store, etc, is under construction, they cannot really meet this requirement.

Background for approval of form for supervisor verification for pharmacy intern application

The Board staff continues to have issues relative to applications for pharmacy intern registrations from graduates of foreign colleges of pharmacy who are not currently living in Virginia and who may not even be in the U.S. yet and are trying to obtain the intern registration in order to be eligible for an H1B visa. The Board closed some loopholes last year with a revision in its application form that requires the applicant to state the name of the pharmacy and supervising pharmacist where they plan to work. However, when we tried to verify the information on one application, the pharmacist named knew nothing about the pending employment and was very upset that her name and license number had been provided as the supervising pharmacist. Whether the prospective employer had given out her name and license number or whether the applicant had simply gotten it from the website, is not known.

Staff would like to have a second form that we send to the pharmacist named on these applications for them to sign that they agree to supervising the applicant.

Draft form attached.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

6603 W. Broad Street, 5th Floor
Richmond, Virginia 23230

(804) 662-9911 (Tel)
(804) 662-9313 (Fax)

Preceptor Verification Form

The following person has applied for registration as a pharmacy intern, indicated this pharmacy as the employer, and provided your name and license number as the supervising pharmacist.

Applicant's Name
Pharmacy Name and Address

Is the person listed above currently working at this pharmacy under your supervision?
Yes ☐ **No** ☐

If no, what is this person's anticipated start date? _____.

By your signature below, you are certifying that you will be supervising the aforementioned person at the location indicated above.

_____ _____
Signature Date

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COMMONWEALTH OF VIRGINIA
Board of Pharmacy

6603 W. Broad Street, 5th Floor
Richmond, Virginia 23230

(804) 662-9911 (Tel)
(804) 662-9313 (Fax)

Application for Registration as a Pharmacy Intern for Graduates of a Foreign College of Pharmacy

Application Fee (Non-Refundable): $15.00

The required fee must accompany the application. Make check payable to "Treasurer of Virginia".

Applicant—please provide the information requested below. (print or type) use full name, not initials

Last Name	First Name	Middle/Maiden Name

Street Address	Area Code and Telephone Number

City	State	Zip Code

Social Security Number or DMV number*	Date of Birth	FPGEC Number

Name of Foreign College of Pharmacy	Date of Graduation	Country of Foreign College of Pharmacy

Name of Virginia pharmacy where you plan to gain your experience	Expected start date of employment

Name of the Virginia licensed pharmacist who will be your primary supervisor for certification of your practical experience	Supervising pharmacist's license number
_____	0202 _____

I certify that the information provided is true and accurate, and that I have obtained the FPGEC. I further certify that I am not already licensed as a pharmacist in any other state in the U.S., that I have not yet obtained the required practical experience to be licensed in Virginia, and that I plan to obtain these hours in a Virginia pharmacy.

_____ _____

Signature Date

1. A legible copy of FPGEC must be furnished with this application in order to be eligible for a Pharmacy Intern Registration.
2. Registration with the Board as a Pharmacy Intern is required *prior to gaining practical experience* in Virginia for licensure as a pharmacist.

FOR OFFICE USE ONLY	
Registration Number 0203-	Expiration Date

*In accordance with § 54.1-116 of the Code of Virginia, you are required to submit your Social Security Number or your control number** issued by the *Virginia* Department of Motor Vehicles. If you fail to do so, the processing of your application will be suspended. This number will be used by the Department of Health Professions for identification and will not be disclosed for other purposes except as provided for by law. Federal and state law requires that this number be shared with other agencies for child support enforcement activities. NO LICENSE WILL BE ISSUED TO ANY INDIVIDUAL WHO HAS FAILED TO DISCLOSE ONE OF THESE NUMBERS. In order to obtain a Virginia driver's license control number, it is necessary to appear in person at an office of the Department of Motor Vehicles in Virginia. A fee and disclosure to DMV of your Social Security Number will be required to obtain this number.

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Background on request from Dr. Amarasinghe:

Please refer to the attached email correspondence with Dr. Amarasinghe related to trying to stop prescription forgeries. He is concerned that pharmacies are not readily catching forgeries because they are not required to have caller ID to know the number from which oral prescriptions are transmitted, and also because a photo ID is not required to pick up a prescription. The process for petitioning for rulemaking was explained to him, and in the series of emails he requested that staff do it for him. I declined to handle the formal petition on his behalf, but thought the most expeditions method of informally handling the matter was to place his request on the Board agenda for a response.

Scotti Russell

Mallory, Tiffany N.

From: Russell, Scotti
Sent: Friday, February 09, 2007 5:01 PM
To: 'Disamodha Amarasinghe'
Cc: Mallory, Tiffany N.; Yeatts, Elaine J.; Casway, Howard (OAG); Lemon, Faye T.; Wingfield, Emily O.
Subject: RE: Rx Abuse

Dr. Amarasinghe,

I will put your request on the next Board meeting agenda which will be March 29, 2007.

Elizabeth Scott (Scotti) Russell
Executive Director, Virginia Board of Pharmacy
6603 West Broad Street, 5th floor
Richmond, VA 23230
(804) 662-9911
(804) 662-9313 Fax
scotti.russell@dhp.virginia.gov
www.dhp.virginia.gov/pharmacy

From: Disamodha Amarasinghe [mailto:drdc2006@cox.net]
Sent: Friday, February 09, 2007 3:47 PM
To: Russell, Scotti
Subject: Re: Rx Abuse

Thanks:

Can you fill the form as required using the suggestions I made and send it back to.
Then I can sign it and return it to you.
If you are not clear of my intentions please let me know.
All I am asking is to stop criminal activity and stop the abuse.
If there is a better way to do that I am open for suggestions.
If this is a legal issue you can run this by the counsel for the Board.
If it is a criminal he will obviously block the caller ID.
There is no other way to stop this unless the pharmacist has caller ID.
I do not understand why that has not been the standard practice.
I have been asked to go to court a few times, which could be nipped in the bud,
if they had caller ID.

Thank you
Dr.DC

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On Feb 9, 2007, at 2:43 PM, Russell, Scotti wrote:

> Dr. Amarasinghe,
>
> Based on your last email, I just sent you some suggested regulation sections for you to use on the form. If you want the Board to consider this, then you really need to fill out the form I sent you and send it in. This is the format we have to use if you want to petition the board to make

new regulations. Doesn't have to be very elaborate, but we do need it.

Thanks,

Scotti

From: Disamodha Amarasinghe [mailto:drdc2006@cox.net]
Sent: Friday, February 09, 2007 2:08 PM
To: Russell, Scotti
Cc: Lemon, Faye T.
Subject: Re: Rx Abuse

Thank Scotti:
I already stated what I have to say. Can you take it from their since it is your department. Do you have any reservations or concerns?
I will also ask Fay Lemmon to review it.
DC
On Feb 9, 2007, at 1:17 PM, Russell, Scotti wrote:

> Dear Dr. Amarasinghe,
>
> Requiring these things of pharmacies would require the Board to include this requirement in its regulations. If you would like for the Board to do this, you will need to submit a petition for rulemaking. I am attaching the form for your convenience.
>
> As a point of reference with respect to ID, the law already gives a pharmacist the right to request identification when dispensing controlled substances, but does not require it. In reality requiring identification will not help when an agent of the patient is picking up a prescription on behalf of the patient, i.e. a neighbor, caregiver, spouse with different last name, etc.
>
> Elizabeth Scott (Scotti) Russell
> Executive Director, Virginia Board of Pharmacy
> 6603 West Broad Street, 5th floor
> Richmond, VA 23230
> (804) 662-9911
> (804) 662-9313 Fax
> scotti.russell@dhp.virginia.gov
> www.dhp.virginia.gov/pharmacy

From: Disamodha Amarasinghe [mailto:drdc2006@cox.net]
Sent: Friday, February 09, 2007 8:56 AM
To: Russell, Scotti
Subject: Rx Abuse

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D.C.Amarasinghe,M.D.
6204 N. Military Hwy.
Norfolk VA 23518
757-855-1900 855-2272 fx

DrDC2006@cox.net www.DCamara.Com

Feb.9, 2007

Elizabeth Scott Russell

Executive Director

Board of Pharmacy
Scotti.Russell@dhp.virginia.gov

6603 West Broad Street, 5th Floor,
Richmond, Virginia 23230-1712.
(804) 662-9911
(804) 662-9313 fx
Complaints: (800) 533-1560

pharmbd@dhp.virginia.gov

Re: **Forging Rx**

Dear Sir

I am having an issue that I need to make some recommendation to correct the problem. I have got many calls from Pharmacists in the past about patients who are either writing prescriptions forging my signature or they are calling in prescriptions in my name. These are usually for controlled drugs like Vicodin etc.

According to the pharmacists some of them are using different names.

In order for the catch these offenders we need to have a better system so that we catch the right person.

I also learned the Pharmacies are.

1. Do not have caller ID in their telephones, which is very inexpensive thing to have.
2. They also do not check a photo ID when they dispense controlled drugs to a patient.

I think we should make these 2 items mandatory requirement for the Pharmacy to do before dispensing controlled drugs. Appreciate your attention to this matter.

Sincerely Yours

<petition pharmacy.doc>

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Russell, Scotti

From: Russell, Scotti
Sent: Friday, February 09, 2007 2:38 PM
To: 'Disamodha Amarasinghe'
Cc: Hickey, Jane (OAG)
Subject: RE:

Dr. Amarasinghe,

You would be amending a body of existing regulations, by adding new requirements for pharmacies.

with respect to question 1 on the form:

for the caller ID requirement, you may want to ask that "18 VAC 110-20-170. Required mimimum equipment or resources" be amended to add caller ID as required minimum equipment.

to require positive identification for picking up a prescription, there are several sections of regulation that could be amended to add this requirement, but perhaps the most appropriate would be 18 VAC 110-20-200 (A) to require that designated persons check ID prior to delivery to the patient.

with respect to question 2 on the form:

this is where you have the opportunity to describe the problem you are having, what it is you want the Board of Pharmacy to do to correct it, and why you consider this to be the appropriate action.

Elizabeth Scott (Scotti) Russell
Executive Director, Virginia Board of Pharmacy
6603 West Broad Street, 5th floor
Richmond, VA 23230
(804) 662-9911
(804) 662-9313 Fax
scotti.russell@dhp.virginia.gov
www.dhp.virginia.gov/pharmacy

From: Disamodha Amarasinghe [mailto:drdc2006@cox.net]
Sent: Friday, February 09, 2007 2:24 PM
To: Russell, Scotti
Cc: Hickey, Jane (OAG)
Subject:

Disamodha. C.Amarasinghe,M.D.
6204 N.Military Hwy.
Norfolk VA 23518

Cell : (757)288-5188
Office: (757) 855-1900
Fax: (757) 855-2272

E-mail DrDC2006@cox.net

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3/21/2007

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

There is apparently no regulation to have caller ID. If the caller claims to be an MD the pharmacist can immidiately know
if it is a doctor who is calling. THere is also no regulation to check the photo ID when they pick up the drug.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

item no.1.

DC

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BOARD OF HEALTH PROFESSIONS
JANUARY 18, 2007

MEETING SUMMARY

- **The American Association of Retired Persons made a presentation on a study that they are undertaking relating to assuring continuing competence in health care providers. They requested ongoing opportunities to share their research with BHP and to seek BHP's input regarding their findings. The matter was referred to the Education Committee for further review.**

- **Sanctions Reference Study - the Board of Veterinary Medicine's system has been finalized and they are scheduled to begin implementation in February. The Board of Optometry's data collection is scheduled to begin in February.**

- **Criminal Background Check Study - Delegate Purkey will be seeking a study from DHP on the implications of requiring checks of health care licensees and applicants.**

- **Agency Performance Measures - the Board was briefed on Virginia Performs and the agency's efforts to meet the new goals.**

- **This year, the Board will be reviewing emergent health professions including consideration of the effectiveness of the current regulations on dialysis technicians and dietitians.**

- **As part of its Board member training efforts, the Board presented brief educational DVDs on mandatory reporting of child and elder abuse. These DVDs were developed for health care practitioner education by the Department of Social Services and are available from them to any interested parties.**

DRAFT

VIRGINIA BOARD OF HEALTH PROFESSIONS
DEPARTMENT OF HEALTH PROFESSIONS
FULL BOARD MEETING
JANUARY 18, 2007

TIME AND PLACE:	The meeting was called to order at 10:10 a.m. on Thursday, January 18, 2007, at the Department of Health Professions, 6603 W. Broad St., 5th Floor, Room 2, Richmond, VA.
PRESIDING OFFICER:	David R. Boehm, President
MEMBERS PRESENT:	Susan G. Chadwick, Au.D. Lynn M. Cooper, Citizen Member Meera A. Gokli, D.D.S. Mary Gregerson, Ph.D. David H. Hettler, O.D. Damien Howell, P.T. Billie W. Hughes, F.S.L. Vilma Seymour, Citizen Member Mary M. Smith, N.H.A. Demis L. Stewart, Citizen Member Lucia Anna Trigiani, Esq., Citizen Member John P. Turner, L.P.C. John T. Wise, D.V.M.
MEMBERS NOT PRESENT:	Jennifer H. Edwards, Pharmacy Juan M. Montero, II, M.D. Joanne Taylor, Citizen Member
STAFF PRESENT:	Emily Wingfield, Chief Deputy Director Amy Marschean, Assistant Attorney General Elizabeth A. Carter, Ph.D., Executive Director for the Board Elaine Yeatts, Senior Regulatory Analyst Susan Stanbach, Senior Management Analyst Faye Lemon, Director, Enforcement Carol Stamey, Administrative Assistant
OTHERS PRESENT:	Kate Nosbich, Deputy Executive Director, Medicine Sammy Johnson, Deputy Director, Enforcement Richard Morrison, AARP
QUORUM:	With twelve (14) members present, a quorum was established.

AGENDA:	Revisions to the agenda were made as follows: AARP presentation was moved to follow the approval of the minutes and the Legislative/Regulatory Update was moved to follow the AARP presentation.
APPROVAL OF MINUTES:	On properly seconded motion by Ms. Cooper, the Board voted unanimously to adopt the minutes of the October 18, 2006 meeting.
PUBLIC COMMENT:	Mr. Richard Morrison, Consultant with AARP, presented a slide presentation on assuring the continued competence of licensed health care practitioners in Virginia. Mr. Morrison requested collaborative input from the Board. The slide presentation is incorporated into the minutes as Attachment 1. **Action** On properly seconded motion by Ms. Trigiani, the Board voted unanimously to refer the matter to the Education Committee for further review.
UPDATE ON LEGISLATION AND REGULATIONS:	Ms. Yeatts presented a summary of the 2007 Legislation that specifically may affect the Department of Health Professions.
REPORT FROM CHIEF DEPUTY DIRECTOR:	Ms. Wingfield, Chief Deputy Director, speaking on behalf of Ms. Ryals, informed the Board of the agency's move this summer.
STRATEGY FOR EDUCATIONAL EFFORTS:	Ms. Jolly presented an update on the Board's educational strategies to enhance transparency, public protection and internal communication developed at the Board's retreat in October. She stated that the development of "how to's" would be forthcoming and communicated through e-mail.
EXECUTIVE DIRECTOR'S REPORT:	**Budget** Dr. Carter noted that the Board continued to stay within its allotted budget. **Sanction Reference Study** Dr. Carter reported that the Board of Veterinary Medicine had been trained in the use of its new Sanctions Reference system. They will begin using the system in February to aid in the case decision making process. Further, that the Board of Optometry had completed its interviews and will begin data collection. The

Behavioral Science Board will begin its interviews in February and the remaining boards will begin their interviews in the Spring.

Criminal Background Check Study
Dr. Carter informed the Board of Delegate Purkey's request for a study on criminal background checks for health care licensees and applicants. She reported that the agency is at its highest number of disciplinary cases and the inclusion of criminal background checks would most likely result in a significant increase in the number of disciplinary cases.

It was requested that renewal cards be revised to include a questionnaire statement regarding criminal history within the last year.

Ms. Faye Lemon, Director of Enforcement, briefed the Board that she had begun the process of holding open dialogue sessions with the various boards and associations.

Agency Performance Measures
Dr. Carter presented a summary of the agency's key performance measures:
(1) Resolve 90% of disciplinary cases within 250 days;
(2) Up the customer satisfaction surveys from 94% to 97%; and
(3) Complete 90% of licensure applications within 30 days after receipt of all required items.

Task force on the definition of patient care?????
More dialogue among boards and staff?????

Dr. Carter also reported that the Board will begin the process of reviewing emerging professions and the various boards will be contacted for their input. Additionally, the current regulations of the dialysis technicians and dietitians and nutritionists will be reviewed for effectiveness in protecting the public. Dr. Carter also reported that staffing and enforcement processes of other states would be conducted.

QUESTION ABOUT BOARD REPORTS:

Mr. Boehm polled the board members regarding the presentation of individual board reports. It was the consensus of the Board that only items of interest to

other boards be presented at the full board meeting.

NEW BUSINESS:

Mr. Boehm requested that members submit suggestions for continuing education items for presentation at future board meetings. Dr. Gregerson requested that Dr. Carter present an overview of the CAC meeting.

Ms. Cooper reported that the Board of Nursing had received presentations from HPIP and Mr. Casway. She noted that both presentations were beneficial to the Board in case adjudication.

ADJOURNMENT:

The meeting adjourned at 1:40 p.m.

David R. Boehm, L.C.S.W.
Board President

Elizabeth A. Carter, Ph.D.
Executive Director for the Board

Attachment 1

Advancing the Safety and Quality of Health Care
assuring the continued competence of licensed health care practitioners in Virginia

Who We Are

☐AARP, more than 38 million members
☐AARP Virginia, nearly one million members
☐Citizen Advocacy Center, providing training and support for public members of licensing boards

AARP Virginia
Task Force on Health Care Reform
☐Charles Alexander
☐Kaye Berry
☐Raymond Boyd
☐Gerri Holmes
☐Dan Johnson
☐Richard Lindsay MD
☐William Lukhart
☐James Moore
☐Richard Morrison PhD
☐Nancy Roberts

☐Kenneth Olshansky MD
☐Joseph Sailor
☐Donald Simpson
☐Edward Susank
☐Neil Walsh
☐Rose Wesson
☐Bill Kallio, Madge Bush and Amy Gilbody, AARP/VA
☐Ilene Henshaw and Joyce Dubow, AARP National

Why We're Concerned
☐Continued problems with patient safety and health care quality
▪44,000 to 98,000 preventable hospital deaths annually
▪Gap between "best practices" and actual practices: fewer than ½ of Americans receive recommended care
☐Practitioner competence & system safety issues
☐CE alone has little impact on practice performance
☐Virginians overwhelmingly support continuing competence requirements for health practitioners

Sources

- Fifty years of policy studies
- IOM studies on safety and quality of care
- Pew Health Professions Commission recommendations
- McGlynn et al. "The Quality of Health Care Delivered to Adults in the US" NEJM June 2003
- Continued initiatives of the Citizen Advocacy Center
- AARP Public Policy recommendations 2000-2006
- AARP Public Policy Institute report on "Implementing Continuing Competency Requirements for Health Care Practitioners" (2006)
- "Strategies to Improve Health Care Quality in Virginia" AARP Survey January 2007 (in print)

Licensing Boards are the Key

- Only licensing boards may impose requirements for initial and continued competence for all practitioners.
- Federation of State Medical Boards, National Council of State Boards of Nursing, National Association of Boards of Pharmacy and other national licensing associations agree that licensing boards have a responsibility and duty to assure the continued competence of licensees

Why Virginia?

- A history of leadership among all states in protecting the public
- The unique structure:
  - Board of Health Professions oversight
  - Requirement for public members on all licensing boards
  - All boards can make regulations necessary to assure continued competence (Code § 54.1-103A and §54.1-201.5)
- BHP's historic concern for improving continuing professional development programs
  - "*Continuing competence is one of the dominant issues in professional regulation. The community of regulators acknowledges the need for prevention and agrees that some system for monitoring the acquisition of knowledge, skills and ability of health care practitioners is a warranted use of state regulatory powers.*" (1985)
  - Adoption of six principles for evaluating existing and proposed competency requirements (1992) in response to growing numbers of boards imposing traditional CE requirements.

BHP's Six Principles for CPD

- Evidence-based
- Require demonstration of acquired competency
- Credible and relevant to changing environment
- National level of evidence

□Administratively feasible, cost-effective and equitably applied and enforced
□Least restrictive provisions consistent with public protection

Application of the Principles

■BHP has the statutory duty and authority "*to promote development of standards to evaluate the competency of healthcare professions*" (Code §54.1-2510.9)
■JLARC reported the Board's performance relative to this authority as "*unsatisfactory*" (House Document 31:1999, p. 63). A lack of resources was cited as a major problem.

AARP Recommended Standards

□State laws and implementing regulations should require that – as a condition of relicensure – licensees participate in periodic continuing professional development programs that include:
■Assessment
■Execution of a learning plan based on that assessment
■Periodic demonstration of continuing competence

Continuing Education (CE) ≠ Continuing Professional Development (CPD)

□Meta-analyses show that *traditional* CE is not effective in changing performance. We know what works best, but we consistently use CE methods that are the least effective (Davis et al. JAMA 1991, 1995, 1999)

How AARP Virginia Can Help

□In collaboration with BHP:
■Assess safety and quality issues that are Virginia-specific
■Tabulate, in detail, the continuing education/continuing competence requirements for all professions regulated by DHP Boards
■Assess these requirements against the standards recommended by BHP and AARP
■Report and update findings and recommendations to BHP at each quarterly meeting in 2007
■Recommend any legislation required to assist boards in meeting the recommended standards

What We Ask of BHP

□Approval to pursue this work in collaboration with the Board and its Executive Director
□Consideration of the findings and recommendations of our work throughout the year
□Development of guidance documents to help boards implement CPD programs that meet BHP and AARP standards
□*At the Board's sole discretion*, endorsement of the findings and recommendations of our collaborative effort -- including proposed legislation -- at the end of the project (October 2007)

Questions? Contacts

□Bill Kallio, State Director, AARP Virginia

☐Madge Bush, Associate State Director for Advocacy AARP Virginia
☐Richard Morrison, Coordinator for the Review
☐David Swankin, President/CEO, Citizen Advocacy Center

Contact Information:
☐AARP Virginia
■Madge Bush mbush@aarp.org (804) 344-3059
■700 West Main Street Suite 901
■Richmond, VA 23219
☐Citizen Advocacy Center (202) 462-1174
■David Swankin www.cacenter.org
■1400 Sixteenth Street Suite 101
■Washington, DC 20036

THANK YOU
☐AARP National Office

☐AARP Virginia

☐The Citizen Advocacy Center

☐The citizens of the Commonwealth of Virginia